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SU CL FIELD OF THE INVENTION

P The present invention relates to the field of dispensing medication to a living being. Although mainly intended for use by human patients requiring infusions of a drug, such as insulin, glucose, heparin, or any of various other chemotherapeutic agents, the invention extends to use in any living body (such as domestic animals) and to the infusion of any liquid (such as blood) or colloidal suspension, or gas or granulated solid, which may provide a curative or healing effect. Although a principal use envisioned is for implantable devices, it is also envisioned that it could be used external to a living being for the infusion of medication.

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IMPLANTABLE, PROGRAMMABLE MEDICATION  
INFUSION SYSTEM

C. TECHNOLOGICAL CONTEXT OF THE INVENTION

P Various techniques and devices have been suggested and are currently under study which address the problem of dispensing a drug or other medicative liquid into a living body. Of these techniques and devices, however, redundant safety features and flexibility achieved by programming dosage inputs are rarely contemplated.

One liquid infusion device discussed in U. S. Patent No. 4077405 by Haerton et al discloses a controllable dosing arrangement which provides for human operator interaction. A syringe forces liquid through a pressure valve into a supply reservoir and a bellows pump forces drug from the reservoir through a flow limiter into the body. Haerton et al teaches an "overpressure" technique where liquid in the reservoir is at a pressure above that at the discharge point. This device fails to address various safety problems such as leakage, excessive pumping, and excessive requests for drug. In particular, should the input control valve in Haerton et al leak, a flood of liquid would enter the body because of the pressure differential and the lack of any back-up safety mechanism. No provision for detecting leaks in the device, for signalling malfunctions, for restricting the number of or quantity of drug doses, or for monitoring proper operation of the device is suggested.

Like Haerton et al, U. S. Patent No. 3692027 by Ellinwood teaches an implanted, self-powered drug dispenser having a bellows pump which is fed through and expels drug through valves, in particular one-way valves. The Ellinwood device is not programmable; it varies

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*See C*

dosage by opening and closing portals or selecting a dose or medication from one of a plurality of pumps having different dosage volumes and/or different medications stored therein. Safety redundancy such as pressure integrity checks during filling, leakage problems, patient and doctor interaction with the dispenser, and dosage input programming are not considered.

*Child M*

An invention of Blackshear (U.S. Patent No. 3731681) shows another infusion pump without redundant safety features. While disclosing an implanted bellows pump arrangement fed through a self-sealing plug, Blackshear does not look for pressure integrity before filling the device with drug. Further, because there is no input valve and because the pressure in the device is above that of the body in which it is implanted, leakage in Blackshear can be dangerous. Further, like Haerton et al and Ellinwood, Blackshear does not disclose an antechamber which can serve various safety purposes.

*Child M*

Richter (U. S. Patent No. 3894538) considers, in a medicine supplying device, one safety feature: an exit plug for preventing contaminants from entering the device and for limiting drug outflow. The flow from the Richter device does not provide a smooth pulsatile flow of drug which is infused over a relatively long period. It further fails to disclose any means for reliably controlling or varying the flow rate.

*Child M*

A device by Jacob (U. S. Patent No. 4033479), like other techniques, provides a bellows pump chamber which maintains drug at a "constant internal pressure." A

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valve opens to release drug into a body and the bellows varies the chamber volume to maintain constant pressure. It is not of importance to Jacob how much pressure there is in the chamber -- it is above body pressure -- but, rather, the concern is to keep pressure constant.

Leakage out from the valve and the spouting of drug into the body under relatively high constant pressure would appear to be problems inherent in the Jacob device.

Several recent publications have also underscored the need for an implantable medication infusion device. *Chub* 37 Two articles by Rohde et al ("One Year of Heparin Anti-  
38 coagulation;" Minnesota Medicine; October, 1977 and "Protracted Parenteral Drug Infusion in Ambulatory Subjects Using an Implantable Infusion Pump"; American Society for Artificial Internal Organs Transactions, Volume XXIII; 1977) describe an implantable infusion pump which comprises a hollow disk separated into two chambers by a bellows. A volatile fluorocarbon in the outer chamber forces drug from the inner chamber through a filter and catheter into a patient. Filling of the inner chamber is accomplished by penetrating a self-sealing septum which apparently forms a wall of the inner chamber... The condensation of the fluorocarbon provides energy for cyclical pumping. No antechamber, no check for pressure integrity before filling or during operation, no programming means, and no patient or doctor interaction with the device are contemplated.

*Chub* 37 Finally, an article by Spencer ("For Diabetics: an  
38 electronic pancreas;" IEEE-Spectrum; June, 1978)

discusses current trends in the implantable drug pump field. Programming the rate of drug flow over time depending on food intake is mentioned. Efforts in the development of an implantable bellows pump are also discussed. Spencer further mentions the use of alarm sounds if a pump fails to provide drug in accordance with the preprogrammed rate. The Spencer article generally discusses drug dispenser technology but fails to address many specific problems. As in other cited work, redundant safety features such as an antechamber; leak detection; distinctive subcutaneous stimulation to indicate various device malfunctions; safe method of programming the device regardless of work, food-intake, or time schedules; and maintaining the reservoir pressure below ambient body pressure so that a leak would result in body fluids being inadvertently released into <sup>16</sup> dose of drug entering the body (at a high, constant <sup>17</sup> pressure) are not considered.

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### SUMMARY OF THE INVENTION

P. In a field where safety and reliability are paramount, the present invention provides extensive redundancy to prevent device failure.

The present medication infusion system provides an antechamber which is normally filled with saline solution to act as a buffer between the medication intake point and the major medication reservoir in the device. The reservoir may contain a fatal amount of drug or other medication. It is thus isolated from the body by a filter, one-way inlet valve, the saline-containing antechamber and a septum providing a self-sealing opening to the antechamber. Further, the reservoir is at a pressure below the ambient body pressure. Thus, even if the inlet valve and septum leak, body fluids would enter the antechamber and slowly ooze into the reservoir through the flow-impeding filter. Any other leak of medication from the reservoir would be sensed by a fluid detector outside the reservoir. Similar safety back-ups are provided at the outlet output of the reservoir which is provided with two one-way valves and a filter.

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The outlet, however, also is provided with a deformable wall which combines with the outlet filter to yield an exponentially decaying flow of medication. This smooth flow over a long, predetermined period provides enhanced safety and flow control. Also at the outlet is an element for correlating medication requests with medication dispensing, thus providing an operational indicator and safety feature.

In. C4

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Also, for safety, a filling procedure is provided which insures that medication is not injected into the device until pressure integrity at the input is determined.

In the mechanical pump itself, the amount of medication pulsing it can provide is restricted by a pressure limit intrinsic in the pump design.

In programming the present system, convenience and safety are again major concerns. A flexible, maximum running integral program for limiting medication dosage inputs communicated by a patient satisfies not only a patient's need for proper amounts of medication but also satisfies a variable work and eating schedule requirement of the patient. In addition to a programmable rate of medication input, a hardwired limit is also included. If requests exceed the limits set by the program, the hardwired limits will inhibit the pulsing of excessive medication into the patient.

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Finally, the system provides a history of medication infusion which a physician can read out through telemetry means. This telemetry means is also used to program and check the system.

DESCRIPTION OF THE DRAWINGS

C Figs. 1 and 2 show a front and top view, respectively, cross-sectional of the implantable portion of the present medication infusion system.

a Fig. 3 shows, in detail, the mechanical construction of a pulsatile pump element of the invention.

a Fig. 4 is a block diagram showing the electronics of the invention.

C 5 6 shows a method  
Figs. 5 and 6 show alternative methods of programming the rate of medication infusion into a patient by use of the maximum running integral dosage limiting technique.

D a 7 8 Figs. 7 and 8 are illustrative of a patient programming unit. Fig. 7 shows a front view illustrating a sample apparatus for selecting dosage depending on recognized body condition factors. Fig. 8 shows a rear portion which provides information relative to the last programming of the patient programming unit.

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DESCRIPTION OF THE INVENTION

Referring to Fig. 1, the various portions of the implantable programmable medication infusion system are shown. An implantable portion 2 in a patient's body can be programmed either by the <sup>medication</sup> programming system 1 or by the patient's programming unit 400. Commands from the <sup>medication</sup> programming system 1 emitted from the communication head 300 are <sup>transmitted</sup> telemetered to electronics in the implantable portion 2 in order to program and effectuate the infusion of medication into the body in a safe, controlled fashion. The medication programming system 1 is also capable of reading information out of the implantable portion 2 concerning the amount of medication dispensed over a specified time period and furthermore the medication programming system 1 is capable of calibrating the per pulse of medication of the implantable portion 2. A medication injection unit 7 is connected to a double hypodermic syringe 4 which is used to provide medication to an implantable medication reservoir 18 (shown in Figs. 2 and 3) included within the implantable portion 2. Fill commands to the medication injection unit 7 emanate from a medication programming unit 3. A patient's programming unit 400 is controlled by the user to request doses of medication. The dosage requests are controlled by safety units embodied in fixed hardware elements and programmable elements found in the implantable portion 2. To recharge a rechargeable cell contained within the implantable portion 2, an external charging head 9 connected to a battery charging unit 11 is included. The need for the charging head 9 and battery charging unit 11 can be obviated by the inclusion in the implantable portion 2 of a power supply (such as a lithium cell) which is of sufficient lifetime

to negate the need for recharging. The medication programming unit 3 outputs to a paper printer 13 which provides hard, readable output that can be readily interpreted by a physician.

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Referring now to Figs. 2 and 3, the implantable portion 2 of an implantable programmable medication infusion system is shown. Medication is provided to the implantable portion 2 by means of a double hypodermic syringe 4 which penetrates the skin 5 and a self-sealing rubber <sup>septum</sup> diaphragm 6 which covers an antechamber 8 in leak-proof fashion. Medication is introduced into the antechamber 8 through syringe 4 under pressure the level of which is controllable externally. A reservoir chamber 10, in which the medication is stored under relatively constant pressure, is fed from the antechamber 8 via a ceramic filter 12 and an inlet pressure valve 14 which permits flow only from the antechamber 8 into the reservoir chamber 10 when the pressure differential between them exceeds a predetermined threshold.

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The inlet ceramic filter 12 performs various functions. Besides filtering contaminants from medication being fed into the reservoir chamber 10, the ceramic filter 12 serves to limit the rate of medication flow from the antechamber 8 into the reservoir chamber 10 or, conversely, from the reservoir chamber 10 into antechamber 8 should the inlet pressure valve 14 leak or malfunction.

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Further, should the self-sealing rubber <sup>septum</sup> diaphragm 6 leak, the ceramic filter 12 together with the inlet pressure valve 14 prevents the inflow of body fluids into the

reservoir chamber 10. Further, should the inlet pressure valve 14 and the septum 6 both leak or otherwise malfunction, the inlet ceramic filter 12 would permit only a slow flow of body fluids to enter the reservoir chamber 10, until body ambient pressure is achieved, at which time some ~~drug~~ <sup>medication</sup> could diffuse through the ceramic filter 12 but at a rate that would not be hazardous to a typical patient in which the system would be implanted.

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3) 20  
The reservoir chamber 10 comprises a liquid-vapor portion 16 which rests atop a reservoir of medication 18, the vapor portion 16 and the reservoir 18 being separated by a flexible <sup>liquid</sup> ~~membrane~~ <sup>diaphragm</sup> 20. The liquid-vapor volume in the vapor portion 16 preferably comprises a saturated vapor in equilibrium with a small amount of Freon 113 liquid. Over normal body temperatures, Freon 113 has a linear pressure characteristic ranging from -4 psig (at 98°) to approximately -2.5 psig (at 104°F). Using Freon 113, the medication reservoir 18 will be maintained at a pressure below that of the human body pressure up to altitudes of 8500 feet. For patients who may live above that altitude, other fluorcarbons at lower pressure may be employed. In this way, should both the septum 6 and the inlet pressure valve 14 leak, the effect would be to cause body fluids to diffuse slowly, via the inlet ceramic filter 12, into the medication reservoir 18 rather than to have a rapid flow of medication enter into the body where it could cause harm to the patient. Because of the pressure differential between the body and the medication reservoir 18, medication will not flow from the reservoir 18 into the body. As the amount of medication in the medication reservoir 18 varies, the flexible diaphragm 20 moves up or down, with the Freon 113 being converted either from

liquid to vapor or vapor to liquid to provide an essentially constant pressure which will always be below one atmosphere and below normal body pressure. A reservoir chamber having a volume of approximately 10cc would be sufficient for most applications. This amount of concentrated medication, insulin for example, could be fatal if injected over a short time. The volume of the antechamber 8 is less than 10% the size of the reservoir chamber 10. In the worst case of leakage if medication leaked from the reservoir chamber 10 into the antechamber 8 and even if the antechamber 8 leaked as well, only diluted medication would enter the body gradually passing from an area of low pressure to one of higher pressure. There is thus little likelihood of the dose being fatal. As readily seen in Fig. 2, decreasing or expanding the size of the reservoir chamber 10 would be a simple modification because of the arrangement of elements in the system. Included in the reservoir chamber 10 is a dual pressure switch 22 which can comprise a reservoir fill switch 23 for indicating when the pressure in the reservoir chamber 10 reaches a predetermined level such as -2 psig and a second switch 25 for indicating when the pressure reaches -1 psig. Fill switch 23 is used during the filling procedure to indicate (by a telemetry system to be described later) when the level of medication in the reservoir chamber 10 has reached a specific value. Should body fluids leak into the medication reservoir 18 for any reason, an increase in pressure would result that would activate the second pressure switch 25. For example, when body fluids entering reservoir 18 reach a pressure of -1 psig, this would set off a subcutaneous electrical stimulation alarm system. By having the fill switch 23 set at a

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lower pressure than the body fluid leak detection pressure switch 25, the filling of the reservoir 18 can be accomplished without setting off an alarm signal.

In order to fill the reservoir chamber 10 with medication, a sequence of steps is followed. The antechamber 8 is normally filled with a saline or other innocuous solution which provides a buffer between the body and the reservoir chamber 10 and which if the septum failed would cause no harm to the patient. At the time of filling, a double hypodermic syringe 4 is directed into the antechamber 8 and saline is introduced into the antechamber 8 through one needle and exits through the other in order to flush the antechamber 8 with more saline. Once flushed, the antechamber 8 is checked for ~~pressure integrity with saline introduced under a~~ pressure integrity with saline introduced under a pressure which is less than that required to open the inlet pressure valve 14. When pressure integrity is determined, the antechamber 8 is flushed with the desired medication (such as insulin). Medication is then forced into the antechamber 8 at a pressure greater than that required to open inlet pressure valve 14. The insulin fills the medication reservoir 18 of the reservoir chamber 10 until the flexible membrane 20 contacts the dual pressure switch 22, forcing the reservoir fill switch 23, to generate a signal (e.g. at -2 psig) which indicates that the filling has been completed. The amount of medication required to fill the medication reservoir 18 is noted and then the antechamber 8 is flushed once again with innocuous saline solution. The entire reservoir chamber 10 is surrounded by a wall 24 and is isolated from the other elements of the system by means of the inlet pressure valve 14 and an interface pressure

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valve 26 which connects the reservoir to a pulsatile pump 28 which is shown in Fig. 4. The remaining elements of the implanted portion 2 are also shown in Fig. 2: an electronics section 30 with a battery subsection 32. As

is readily seen in Fig. 2, a hermetically sealed enclosure 34 surrounds the reservoir chamber 10 as well as the pulsatile pump 28 (see Fig. 4) <sup>and the</sup> electronics section 30, <sup>with the battery subsection</sup> <sup>a</sup> <sup>and battery section 32.</sup> To provide an enhanced safety feature, a fluid detector 35 is provided between the wall 24 and the hermetically sealed enclosure 34. Should either the outer hermetic enclosure 34 leak or should the reservoir chamber 10 leak, the fluid detector 35 is placed at a location where the leaking body fluids or medication would be detected. The fluid detector <sup>35</sup> could be a very high resistance <sup>resistor</sup> (e.g. 10 megohms) whose resistance drops significantly in the presence of fluids. A malfunction signal to warn the patient if such a leak is detected, is provided. Similarly a medication leakage detector 37 in the liquid-vapor volume 16 would indicate when medication was leaking into that chamber 16. This detector may also be a resistor whose value will be significantly altered by the presence of the medication. The medication leakage detector 37 when actuated would set off a distinct subcutaneous electrical stimulation alarm signal that can be detected by the patient.

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Fig. 4 illustrates the pulsatile pump 28 shown in the top view of the implanted portion 2 shown in Fig. 3. The interface pressure valve 26 shows where medication enters the pulsatile pump 28 when the differential in pressure between the reservoir chamber 10 and a medication storing means 200 (inside the pulsatile pump 28) reaches a level sufficient to open the inlet ~~pressure~~

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- 7 -

pressure valve 26. In the preferred embodiment shown in Fig. 4, this differential in pressure is caused by the expansion of a spring bellows 202 in response to an electrical pulse introduced to a pulsing coil 204 which surrounds a plate 206 which is attached to the spring bellows 202. When a pulse passes through the pulsing

C coil 204, plate 206 ~~withdraws~~ is driven to a forward stop 208.

a This action of expanding the storing means 200 causes <sup>the</sup> interface pressure valve 26 ~~to~~ open, thereby allowing

a interface pressure valve 26 ~~to~~ open, thereby allowing medication from the reservoir chamber 10 to fill the

a ~~drug~~ <sup>medication</sup> storing means 200. The plate 206 is a permanent

C magnet (or, possibly, a <sup>magnetic</sup> ~~magnetizable~~ material) which moves in response to a current induced magnetic force. When current in the pulsing coil 204 ceases, the spring force of the bellows 202 returns the plate 206 to a position against a backstop member 210. The amount of travel of plate 206 is thus fixed, rendering the stroke volume of the pulsatile pump 28 constant and independent of the electrical pulse current or pulse width into the pulsing coil 204 as long as certain minimum currents and pulse width is provided. The maximum pressure that can be exerted by the pulsatile pump 28 is dependent on the

a spring force that can be exerted by the bellows <sup>202</sup> as well as the cross sectional area of plate 206 which is in contact with the medication in the storing means 200.

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Insc. a c More simply,  $P_{max} = \frac{F}{A}$ , where  $P_{max}$  is the maximum pressure within the <sup>medication</sup> ~~drug~~ storing means 200, F is

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*Ino C8* *a*

the spring force of bellows 202, and A is the portion of  
surface of plate 206 which is in contact with the medi-  
cation in the ~~drug~~ storing means 200. Should a malfunction  
occur in the electronics and a continuous sequence of  
rapid pulses be introduced to the pulsing coil 204,  
causing the plate 206 to reciprocate, the return of the  
plate 206 to its original position against the backstop  
member 210 would be inhibited once the pressure in the  
storing means 200 exceeded  $p_{max}$ . The possibility of  
introducing drugs or <sup>other</sup> medication at an unsafe high pres-  
sure or high rate is thus essentially eliminated.

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An outlet pressure valve 212 connects the storing  
means 200 in the pulsatile pump 208 with an outlet chamber  
214. In operation, when the plate 206 returns toward its  
original position against backstop 210 after being  
reciprocated by the action of the pulsing coil 204 and the  
bellows 202, an increase in pressure in the storing means  
200 results. When the pressure differential between the  
pressure in the storing means 200 and the pressure in outlet  
chamber 214 exceeds that required to open outlet pressure  
valve 212, medication flows into outlet chamber 214 from the  
~~drug~~ <sup>medication</sup> storing means 200. To prevent large spurts or  
pulses of medication from entering the body over a short  
period of time, an elastic wall 216 and an output ceramic  
filter 218 are provided at the entrance to the outlet 220  
of outlet chamber 214. The output ceramic filter 218  
<sup>medication</sup>  
serves to resist the flow of ~~drugs~~ from the outlet chamber  
214 into the living body. The elastic wall 216 acts as a  
type of capacitance to flow, deforming when a pulse of  
medication is fed into the outlet chamber 214. The  
combination of the elastic wall 216 and the output  
ceramic filter 218 comprises a fluid or mechanical RC  
network that provides medication into the body within

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an initial rise followed by a decaying flow. The time constant which is fairly long, is determined by the elasticity of the elastic wall 216 and the resistance of the output ceramic filter 218. In addition, the output ceramic filter 218 disallows medication from being diffused into the body at a high rate, should both the interface pressure valve 26 and the outlet pressure valve 212 fail to seal.

Should valve 212 leak, there would be a slow diffusion of ~~drug~~ <sup>medication</sup> through the ceramic filter 218 until the pressure in the storing means 200 is essentially equal to ambient body pressure. However, since the volume means 200 is very small and since the ~~drug~~ <sup>medication</sup> fluid is essentially incompressible, very little ~~drug~~ <sup>medication</sup> can diffuse out and that amount only at a slow rate. Should both valves 26 and 212 leak, body fluids would then diffuse into the reservoir 18 because it is at a pressure below body ambient pressure. The ~~drug~~ <sup>medication</sup> then could not diffuse through the outlet ceramic filter 218 at an unsafe rate.

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Ino. C12*

Safety of the output is best understood by considering the various pressure levels in the pulsatile pump 28. With a bellows spring force which gives a maximum pressure,  $p_{max}$ , of 15 psig and with an outlet pressure valve drop of 5 psi, it is possible for the pulsatile pump 28 to provide a pressure as high as 10 psig in the outlet chamber 214. The pressure in the outlet chamber 214 is significantly greater than the body ambient pressure of approximately 0 psig or the diastolic blood pressure which is approximately 2 psig. The resistance of the output ceramic filter 218 is selected to limit the drug flow to a given safe level, for example less than 50% the maximum pumping flow at which the pulsatile pump 28 is designed to operate. As with the inlet ceramic filter 12 (of Fig. 2)

the outlet ceramic filter 218 also filters out contaminants moving in either direction, from the outlet chamber 214 into the body or from the body into the outlet chamber 214. Also included in the pulsatile pump 28 is a pressure transducer 222 which is <sup>shown</sup> <sub>optimally</sub> located in the outlet chamber 214. The pressure transducer 222 <sup>produces</sup> <sub>C13</sub> pulses an electrical output when a pressure pulse of medication enters the outlet chamber 214. The pressure transducer 222, in other words, detects the pressure pulses which are provided each time the spring bellows 202 returns the plate 206 to its original position against backstop 210. By comparing the pulsing from pulsing coil 204 with the pulsing generated by pressure transducer 222, an indication is given as to whether an absence or insufficient number of pulses or medication have been provided to the body. An indication of extra pulses of medication compared to the number of electrical pulses may also be provided.

The pulsing signal to pulsing coil 204 as well as the pulse output from the pressure transducer 222 are better understood with reference to Fig. 5 a block diagram of the electronics section 30 shown in Figs. 2 and 3. As seen in Fig. 5, the electronics section 30 communicates with a communication head 300 which is external to the body, communicating through skin 5 by means of radio signals. The communications head 300 provides both power inputs and commands, including programmable inputs, to the electronics section 30. Power is provided by means of an alternating field, e.g. a magnetic field, which is communicated to a pickup coil 304 which is implanted

together with the rest of the electronics section 30 in the body. The pickup coil 304 receives an AC power signal from communications head 300 and passes it on to a full wave rectifier 306. One rectified output from the full wave rectifier 306 enters a battery charge control 308 which provides a fixed DC charging signal to a power cell 310. The power cell 310 can be a nickel-cadmium cell which is readily rechargeable off a rectified signal at a typical frequency of 20 kHz. Alternatively, a lithium-type solid state battery can be used instead of the nickel-cadmium cell in which case the charging circuitry would be eliminated, the lithium type battery providing sufficient power over a long term, thereby obviating the need for recharging. The power cell 310 provides a biasing voltage to a transistor switch 312, the output of which enters the pulsing coil 204 previously described in the context of the pulsatile pump 28. In addition to providing power to the power cell 310, rectified power is also introduced to a DC to DC converter 314 the purpose of which is to provide power at the proper levels to the various loads in the system. In addition to the AC power signal, pick-up coil 304 also receives a train of serial digital bits from the communication head 300. The digital bits comprise commands for programmable inputs which are conveyed, via the pickup coil 304 to a command receiver 316. The signals from the command receiver 316 enter a command decoder 318 which determines if the digital bits are in a proper sequence and, if so, what action in the system the commands dictate. It should be noted that

the full wave rectifier 306, the battery charge controller 308, the command receiver 316, and the command decoder 318 are powered only when an AC signal is picked up by the pickup coil 304. This, of course, prevents the possibility of detecting stray signals as commands and provides power savings. To be sure, the power savings achieved could make possible the use of the aforementioned lithium cell which would not require recharging. From the command decoder 318, programmable inputs and other commands can be provided to a number of elements. A programmable base rate is entered into a base rate memory unit 320 which stores a value indicating the number of pulses of medication which are requested to be provided to a patient during a normal preselected period of time. A second programmable input is provided a patient controlled rate memory unit 322 which stores a value indicating a number of pulses of medication that are requested to be introduced into the body over a given period of time during which the patient eats a meal or otherwise alters the chemical balance of the body (as by exercising). Associated with the base rate memory unit 320 is a hardwired base rate limit control 324 which sets a maximum rate that can override requests of the base rate memory unit 320 which are excessive. Similarly, a hardwired patient controlled rate limit control 326 provides a fixed maximum number of pulses which can be provided at a time after a meal or at other times and under other conditions. As long as the base rate and patient controlled rate values stored in memory units 320 and 322 respectively, do not exceed the hardwired values fixed within limit controls 324 and 326, respectively.

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an output pulse is provided to the input of transistor switch 312 to stimulate a pulse output from pulsing coil 204. Should the rate of either memory unit 320 or 322 exceed the hardwired limits in the limit control elements 324 or 326 respectively, a "rate request exceeds limit" signal is fed from the limit control element 324 or 326 into a programmable alarm generator 328 which provides an electrical signal to a stimulation electrode 330 implanted subcutaneously. By the stimulation electrode 330, the patient is informed by means of a subcutaneous stimulation that one of the memory units 320 or 322 is requesting more than the maximum allowable number of pulses.

It should be noted that the signal to the stimulation electrode 330 can serve the dual function of not only providing the patient with a subcutaneous electrical stimulation but may also be the source of a signal detected by the communication head 300 communicated to the patient or his physician either or both that a failure has occurred. As shown in Fig. 5, the electrode 330 will be isolated and should be insulated from the outside of the hermetically sealed enclosure 34 of the implanted portion 2.

A particularly significant feature of the invention resides in the programmability of the alarm generator 328 based on input commands from the command decoder 318. The alarm generator 328 can be switched on or off and the voltage produced by the generator and hence the electrode 330 can be varied in response to signals emanating from the communication head 300 and channeled through the command receiver 316 to the command decoder 318. In addition, to check the proper operation of the

system, the command decoder 318 can receive test signals which can simulate actual occurrences to determine whether the circuitry in the electronic section 30 is operating properly. For example, extra pulses from the command decoder 318 can be entered into the hardwired limit control elements 324 and 326. These extra pulses can be added to the pulses provided by the base rate and the patient controlled rate memory units. in order to exceed the hardwired base rate and the hardwired patient-controlled rate, respectively. When the rates are exceeded, the alarm generator 328 will provide a signal. In this way, the alarm generator 328 can be used to check the operation of the limit control elements 324 and 326 and also familiarize the patient with the corresponding subcutaneous stimulation emitted by the tickle electrode 330. The programmable alarm generator 328 also receives inputs from the pressure switch 22 and the fluid detector 35 both shown in Fig. 2. If body fluids leak into the reservoir 18, the pressure switch 25 will be activated, indicating this fault condition to the patient by means of the activation of the alarm generator 328 and the electrode 330. If the patient was unconscious, voltage levels on the patient's skin at the site of the implanted portion 2 could be used by the physician to indicate if a malfunction has occurred and which malfunction it was. Further, as previously described, should fluid leak out of the reservoir chamber 10 and onto the lining of the enclosure 34 or, alternatively, if body fluid should leak in through the enclosure 34, the fluid detector 35 would sense such leakage and, as shown in Fig. 5, would provide input to the alarm generator 328. Still another input to the alarm generator 320 comes from

the power cell 310 associated with transistor switch 312. The voltage level of the power cell 310 is communicated to the alarm generator 328, a tickle or subcutaneous stimulation being generated when the voltage is below a predetermined level. Finally, referring back to the pulsatile pump 28 of Fig. 4, the electrical pressure transducer 222 provides a signal which is compared to a programmed "insufficient rate" value emanating from the command decoder 318. If the number of pulses sensed by the pressure transducer 222 over a specified period of time are less than the number of pulses associated with the "insufficient rate" command input, a pulse rate detector 332 will provide an output indicating that an insufficient amount of medication is being provided to the patient over the specified time. The output of pulse rate detector 332 (Fig. 5) also enters the tickle generator 328 to provide a subcutaneous tickle detectable by the patient. It should be noted that the various mentioned failures in the system result in subcutaneous stimulations each of which may be different in stimulation magnitude, duration, or periodicity. For example, the stimulation may range between one to four volts and may vary in frequency above and below 20 pulses per second and most importantly, a variety of pulse patterns may be used each unique to a particular malfunction or warning. Additional warnings that might be used are: (1) medication has leaked into the liquid-vapor volume, (2) only 10% of the medication remains in the reservoir, (3) only 5 days medication remains.

In addition to pulsing the pump coil 204, the outputs of the limit control elements 324 and 326 also provide input to a pulse recorder 334. Pulse recorder 334 maintains a running history of how many electrical pulses have been

provided to the pulsatile pump 28 since the last refill of the reservoir 18 (in Fig. 1). An "interrogate" signal from the command decoder 318 instructs the pulse recorder 334 to provide the history to a telemetry transmitter 336 which communicates the pulse history to a telemetry coil 338. The pulse recorder 334 would record both the number of pulses delivered to the pumping coil 204 and the number of pulses detected by the pressure transducer 222 and/or the difference between these two numbers. The telemetry coil 338, in turn, provides its output through radio frequency signals to a telemetry receiving antenna in the communication head 300. In addition to the pulse history the telemetry transmitter 336 also receives, during programming, inputs from the base rate memory unit 320 and patient controlled rate memory unit 322 which ~~trans-~~  
<sup>are transmitted</sup> C  
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C  
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are also conveyed by means of the telemetry transmitter 336 back to the communication head 300 that the desired base rate and patient controlled rate, respectively, have been programmed into the corresponding memory unit 320 or 322. Similarly, other key parameters <sup>of</sup> ~~trans-~~  
<sup>A</sup> of the system are also conveyed by means of the telemetry transmitter 336 back to the communication head 300. For example, the exact pressure transducer output waveform would be telemetered. Of course, the pressure waveform signal would only be transmitted when the telemetry system is powered. Similarly, the reservoir fill switch 23 placed in the reservoir chamber 10 to indicate when it has reached a predetermined fill level is also connected via the telemetry transmitter 336 and telemetry coil 338 to the communication head 300 to indicate when the reservoir 18 has been filled with medication. Finally, a simulated low battery voltage signal can be conveyed from the command decoder 318 to the telemetry transmitter 336 to check that portion of the status circuitry. As with the

full wave rectifier 306, battery charge control 308, command receiver 316, and command decoder 318, the telemetry transmitter 336 is powered only during programming, <sup>interrogation</sup> testing with simulation signals, and power cell charging.

Reference is now made to Fig. 6 which shows a method of programming the patient controlled memory unit 322. The significance of the method lies in the fact that it provides two maximum running integral dose limits in response to requests for medication. Two maximum integral number of pulses for two different time periods <sup>both are</sup> are provided, ~~and they are both~~ independent of the time of day and therefore would be effective regardless of <sup>A</sup> the patients <sup>schedule</sup> change which schedule <sup>13</sup> might be a result of the patient changing time zones. In the sample graph of Fig. 6, a maximum of eight pulses for a four hour period and twenty-four pulses for any twenty-four hour period are imposed as maximum running integral dose limits. These rate settings can, of course, be altered depending on patient needs and medication to be administered and time periods other than 4 hours or 24 hours could be used. In Fig. 6, the number of pulses is shown as a function of time.

In Fig. 6, at midnight, the number of pulses that are allowed in the 4 hour period is eight. Shortly after 8 A.M. five pulses are requested diminishing the number of additional pulses allowed to three pulses. Prior to noon, within the four hour time period, a five pulse request is entered. In accordance with the maximum running integral four hour restraint, only three pulses are permitted but the remaining two pulses in the request are stored in the memory unit 322 (Fig. 5) to be

executed at the end of the four hour period beginning immediately after four hours past the delivery time for the after breakfast pulsing. Shortly after noon, when the four hours are over the two pulses are executed. It should be noted that shortly after noon the three pulses provided just before noon were subtracted from the eight pulse allowance. The dispensing of three pulses prior to noon is not eradicated until four hours thereafter, or shortly before 4 P.M. Shortly before 4 P.M. the three pulse allowance is automatically raised to six pulses, accounting for the three pulses executed just before noon. Shortly after 4 P.M., the allowance automatically rises to eight pulses thereby accounting for the two pulses executed shortly after noon. At approximately 6 P.M. the patient has dinner requiring five pulses and the allowance diminishes to three pulses. Shortly before 10 P.M. the patient has a snack which requires two pulses of medication diminishing the allowance to one pulse. At approximately 10 P.M. the five pulses provided at dinner are no longer of import and the allowance is raised by those five pulses to a six pulse level allowance. The importance of Fig. 5 is readily apparent when one considers the various time zones or work schedules a patient may go through from time to time in the course of his life. The program in Fig. 6 provides sufficient safety and flexibility for a wide variety of patients.

Referring now to Fig. 7, the front view of a patient programming unit 400 is shown. In the center of the unit is a dial 402 which can be rotated to indicate the size of a meal eaten by the patient or the amount of exercise <sup>exerciser</sup> he has undergone, in order to provide inputs indicating the amount of medication needed. Output

In. C15

- 19 -

from the patient programming unit 400 enters the telemetry input portion of the communication head 300 of Fig. 4 as commands. Whether or not the request is valid is determined in the electronic section 30 and is conveyed back to the ~~patient programming unit 400~~ by telemetry. A signal <sup>400</sup> ~~400 to the patient~~ from the patient's programming unit indicates whether his request has been satisfied. The patient programming unit 400 will be provided both with audio and visual outputs rendering it particularly useful for those patients having either visual or hearing handicaps.

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In Fig. 8 is the rear view of the patient programming unit 400. The rear side of the patient programming unit 400 will provide information indicating the number of pulses sent at the last request ~~403~~; the time of the last request ~~404~~; and possibly (but is not shown) the number of pulses which can be sent within the program restraints. By programming ROMS (not shown) in the patient's programming unit 400 in accordance with the running integral programs shown in Fig. 5 an "OK" or "TOO MUCH REQUESTED" video and/or audible output can be provided. The audio output would emanate from the loudspeaker 405. When the request leads to the dispensing

In. C16

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In. C17

It should be understood that alternative embodiments are contemplated by the present invention. For example, the antechamber 8 can comprise a vitreous carbon insert in the skull coupled with a tube directed to the

In. C18

reservoir chamber 10. The filling procedure and elements of the antechamber 8 (e.g. the <sup>cavum</sup> ~~septum~~ diaphragm 6) would remain the same with the vitreous carbon insert. The inlet

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pressure valve 14 and filter 12 would still separate the

insert and tube from the reservoir chamber 10. Similarly,  
a  
3 in addition to the patient's programming unit 400, a physician's unit may be provided which indicates: when the medication reservoir 18 (of Fig. 1) has been filled, the pulse history from the pulse recorder 334, and other signals from the telemetry transmitter 336 of Fig. 4.  
3 Such a physician's unit would be connected to the <sup>portion</sup> telemetry <sup>output</sup> of the communication head 300.